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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/764,324 | 01/16/2001 | Hui Wang | 3262.1 | 7505 |

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EXAMINER

MORAN, MARJORIE A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631 | 13 |

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/764,324 | WANG ET AL. |
| | Examiner Marjorie A. Moran | Art Unit 1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 March 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) 1-12 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 13-30 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 03 October 2002 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on 03 October 2002 is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

Election/Restrictions

Applicant's election of Group II, claims 13-30 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

An action on the merits of elected claims 13-30 follows.

Drawings

The proposed substitute sheets of drawings, filed on 10/3/02 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(f) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of SEQ ID NO: 3 wherein there is a space between residues 10 and 11 nor for SEQ ID NO: 5 wherein there is a space between residues 2 and 3. Originally filed Figure 7 showed a Sequence A with a period between residues 10 and 11. It is not clear if the period of original Figure 7, or the space in proposed Figure 7 represents a significant "value" in the sequence. Original Figure 7 also shows a Sequence C without spaces. The originally filed specification did not disclose sequences corresponding to SEQ ID NO's 3 and 5. It is noted that the sequence listing was not filed with the original specification, therefore information therein is not considered "originally filed." In addition, formatting used in the sequence listing is not necessarily the same as that used in Figures. As the originally filed Figures do not disclose sequences with spaces therein, and a period has been removed, the

changes proposed for Figure 7 represent new matter, and are therefore NOT approved by the examiner.

It is noted that the "marked up" copy of Figure 7, with proposed changes shown in red ink, does not contain the same changes as are set forth in proposed new Figure 7. The changes shown in the marked up copy of Figure 7 are approved by the examiner; i.e. changes made ONLY to the labels. To reiterate: although the proposed changes made in the marked up copy are approved, new Figure 7 is NOT approved for the reasons set forth above.

Information Disclosure Statement

The IDS filed 5/10/01 as paper #4 has been considered in full.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See e.g. pages 7, 11, and 13. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The specification discloses related applications on page 1. At least one application is identified only by title and attorney docket number, and is incorporated by reference. The specification also discloses, and incorporates by reference, a reference identified only by attorney docket number, on page 12. As one skilled in the art would not be able to identify or access a reference thus identified, the specification also objected to for improper incorporations by reference. Applicant is cautioned to avoid the inadvertent addition of new matter to the specification due to incorporation by reference of articles/applications not specifically identified in the originally filed specification.

The specification incorporates websites by reference on pages 7 and 13. This is an improper incorporation by reference as websites are not static entities and the addition of information or any other material to the website since the time of filing of the instant application would be new matter, therefore the specification is further objected to.

Claim Objections

Claim 14 is objected to because of the following informalities: the term "triming" should be --trimming--. Appropriate correction is required. Claim 21 recites the term "CDS". This abbreviation may have many meanings in the art. The term is identified on page 13 of the specification and is not indefinite. However, for clarity, the examiner recommends that the full term --Coding Regions-- be recited at least once in the claims, preferably with the first recitation of the term "CDS".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 is directed to a method of selecting sequences, but recites method steps cleaning and refining data, then generating consensus or exemplar sequences. No selection step is recited in the claim, therefore it is unclear if applicant actually intends a method of selecting sequences, or intends a method of generating sequences, and the claim is indefinite.

Claim 16 limits the "generating" step of claim 13 to selection of exemplary sequences. The terms "generating" and "selecting" are not synonymous, and are generally accepted to have different meanings in the art. One may generate a variety of consensus sequences, then select one from the variety for further use; or one may select a particular exemplary sequence for generation and testing, but one skilled in the art does not generally think of selection and generation of a sequence as being the same. As it is unclear what method step or steps applicant actually intends, the claim is indefinite.

Claim 19 recites a variable "x" which is limited to not equal n/2. Neither "x" nor "n" are defined by the claim; there is no equation or other algorithm reciting use or calculation of "x" or "n", and one skilled in the art would not know from the context of the claim what "x" or "n" are intended to represent (e.g. the total number of sequences, the contradictory number of sequences, the number of residues in a consensus sequence, the median or average of some other amount, etc.) As the limitations intended by "x" and/or "n" are unclear, the claim is indefinite.

Claim 26 recites the term "P_t" in an equation. The term is not defined in either the specification or claims. If the term is intended to represent a function, then it is unclear what function the function is intended to be. If the term is intended to be a variable, then it is unclear what the variable represents.

Claim 27 recite the term "P" in line 27. The term "P" is not defined by the specification or in the claims. The term "p" is defined in the claims as a probability, but use of a different case indicates that "P" is intended to represent something different from "p".

As variables recite in claims 19-27 are undefined, they cannot be searched. AS the claims specifically recite limitations containing unsearchable variables, claims 19-27 are deemed unsearchable and will not be further treated on the merits with regard to the prior art.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 13 and 15-18 are rejected under 35 U.S.C. 102(a) as being anticipated by MILLER et al. (Genome Research (Nov. 1999) volume 9 (11), pages 1143-1155).

MILLER teaches a method of generating consensus/exemplar sequences wherein raw sequences are cleaned (masked), clusters are refined, and unique consensus sequences generated (p. 1145), thereby anticipating claims 13 and 16. MILLER teaches that his clustering is performed using the d2-algorithm, which is tow-level clustering, therefore claim 15 is anticipated. MILLER teaches that his consensus sequences are generated from clusters by base calling, and teaches that the direction of the consensus sequence may be determined (p. 1146), thereby anticipating claim 17. MILLER does not teach that his directional determination includes contradictory information, therefore claim 18 is also anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over MILLER in view of BURKE et al. (IDS ref: Genome Research (1999) volume 9, pages 1135-1142).

The claims are directed to a method of selecting a sequence wherein sequences are cleaned, clusters are refined and exemplar or consensus sequences are generated. Claim 14 limits cleaning to removing withdrawn sequences, screening, filtering and masking raw sequences, and trimming terminal ambiguous sequences. Claim 15 limits refining clusters to two-level clustering. Claim 16 limits the method to generation of an exemplar sequence. Claim 17 limits generation to generating alignments, calling consensus sequence bases, and determining a consensus sequence direction. Claim 18 limits the determining of sequence direction to one wherein there is no contradictory sequence directions.

MILLER teaches a method of generating unique consensus sequences, as set forth above. MILLER teaches removing withdrawn sequences, screening/filtering/masking raw sequences, and teaches removal of repeat sequences and vector sequences (p. 1145), but does not specifically teach trimming or removing ambiguous terminal sequences.

BURKE teaches removing various 3' sequences when forming clusters (p. 1136).

It would have been obvious to one of ordinary skill in the art at the time of invention to have removed "ambiguous" or any other problem sequences from the termini of sequences (e.g.

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3' sequences), as taught by BURKE, before clustering in the method of MILLER where the motivation would have been to improve accuracy of the clustering, as suggested by MILLER's teaching for removal of repetitive and vector sequences.

Conclusion

Claims 13-30 are rejected; claims 1-12 are withdrawn. The specification is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER



mam
May 31, 2003